

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara Schwalge (for S. Peter Konzel) on July 13, 2010.

2. The application has been amended as follows:

- a. In claim 1, line 2, insert **"(i)"** before the term "forming".
- b. In claim 1, line 10, insert a comma after the term "extruder"
- c. In claim 1, line 10, insert **"(ii)"** before the term "subsequently"
- d. In claim 1, delete the period after the term "composition" and add **"to form the solid dosage forms."**

Therefore, **claim 1** will recite:

A process for producing solid dosage forms, comprising

**(i)** forming a moldable cohesive composition which comprises

- a) 50 to 99.4% by weight of at least one crosslinked nonthermoplastic carrier,
- b) 0.5 to 30% by weight of at least one adjuvant selected from the group consisting of thermoplastic polymers, lipids, sugar alcohols, sugar alcohol derivatives and solubilizers and
- c) 0.1 to 49.5% by weight of at least one active ingredient,

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by heating at a temperature at or above the softening point of the adjuvant, but at least 70°C, in a multi-screw extruder, and

(ii) subsequently cooling the moldable composition **to form the solid dosage forms.**

### ***Reasons for Allowance***

3. The following is an examiner's statement of reasons for allowance: Klimesch et al. (US 5,073,379) teaches a melt extrusion process, but does not teach a high level (50-99.4%) of crosslinked nonthermoplastic carrier. Thacharodi et al. (EP 0 960 620 A1) teaches a process of preparing a granular pharmaceutical composition with a high percentage (10-98%) of carrier such as cross-linked polyvinylpyrrolidone. However, Thacharodi is drawn to granules and not to a moldable, cohesive composition. Therefore, there is no motivation to use the high level of carrier as taught by Thacharodi in the melt extrusion process of Klimesch. Moreover, disintegrants (such as cross-linked polyvinylpyrrolidone) are generally not used in conventional pharmaceutical compositions at levels of 50 to 99.4%, as currently claimed. A further prior art search did not disclose a reference that teaches the process for producing a moldable cohesive composition with 50 to 99.4% by weight of a crosslinked nonthermoplastic carrier.

Therefore, the claimed invention is novel and patentably distinct over the prior art of record.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

5. Claims 1-22 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner  
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